



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0967]

Intent to Exempt Certain Class II and Class I Reserved Medical Devices From Premarket Notification Requirements; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements.” This draft guidance describes FDA’s intent to exempt certain Class II medical devices and certain Class I medical devices, subject to the reserved criteria, from premarket notification requirements. FDA believes devices identified in this guidance document are sufficiently well understood and do not present risks that require premarket notification review to assure their safety and effectiveness. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Abiy Desta, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1682, Silver Spring, MD 20993-0002, 301-796-0293.

SUPPLEMENTARY INFORMATION:

I. Background

In the commitment letter (section 1.G of the Performance Goals and Procedures) that was drafted as part of the reauthorization process for the Medical Device User Fee Amendments of 2012 (Public Law 112-144), FDA committed to identifying low-risk medical devices to exempt from premarket notification. This draft guidance describes FDA’s intent to exempt certain Class II medical devices and certain Class I medical devices that are subject to the reserved criteria of section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) from premarket

submission requirements. FDA believes devices identified in this guidance document are sufficiently well understood and do not present risks that require 510(k) review.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on identifying low risk medical devices to exempt from premarket notification. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements," you may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1300046 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-

3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: July 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.